

REMARKS

Claims 33-35, 38-44, 47-50, 56-59, 61-63, 70, and 72-77 are pending for examination.

Applicant and his representatives thank the Examiner for the courtesy of an in-person interview conducted on August 5, 2008. The present response addresses substantive points discussed during the interview. Specifically, Applicant agreed to provide data showing the effects of L-arginine in a hostile biophysical environment. Accordingly, the present response is believed to constitute a complete written statement of the reasons presented in the interview as warranting favorable action, as required by 37 C.F.R. §1.133.

In addition, Applicant notes that it appears that the Patent Office has withdrawn the finality of the Office Action of January 3, 2008 in view of this most recent Office Action of April 23, 2008. Applicant respectfully requests clarification if this is incorrect.

Applicant also wishes to note that there is a related application that is currently co-pending, Ser. No. 10/201,635, which is a continuation-in-part of the instant application. The Examiner indicated that he was aware of prosecution in that case. Applicant respectfully requests that the Examiner consider the rejections made in Ser. No. 10/201,635 if he has not done so already, as well as the Applicant's recent response in that case.

Rejections under 35 U.S.C. §101 and §112, ¶1

Claims 33-35, 38-44, 47-50, 56-59, 61-63, 70, and 72-77 have been rejected under 35 U.S.C. §101 because the Patent Office states that the disclosed invention is inoperative and therefore lacks utility, and under §112, ¶1, as failing to comply with the enablement requirement. The Patent Office provides Hirvonen, *et al.*, "Effect of diffusion potential, osmosis and ion-exchange on transdermal drug delivery: theory and experiments," *J. Controlled Rel.*, 56:33-39 (1998) ("Hirvonen") as evidence of the inoperability and nonenablement of the present invention as claimed.

Applicant disagrees that the present invention as claimed lacks specific and substantial utility or is not credible, or that the invention is not enabled. As evidence, Applicant provides experimental data, in the form of a declaration, showing that L-arginine in a hostile biophysical environment was delivered to subjects, resulting in increased blood flow and warmer hands,

whereas control experiments lacking L-arginine or a hostile biophysical environment did not show such effects. The conditions used are similar to those described in the application, as discussed in the declaration. Accordingly, it is thus respectfully requested that the rejections under 35 U.S.C. §101 and §112, ¶1 be withdrawn.

The Patent Office bases its rejections exclusively on Hirvonen in stating that the invention is inoperative and nonenabled. However, Hirvonen does not appear relevant to the claimed invention. At the outset, Hirvonen uses cadaver skin while the examples in the instant specification are performed on *live* humans. The properties of dead cadaver skin and live skin are known to be different; thus, it is questionable whether the results of Hirvonen can be accurately compared to live humans. Moreover, Hirvonen is directed to the transdermal drug delivery of sotalol and salicylate. As different compounds may exhibit different degrees of permeability in the skin due to various properties such as size, charge, hydrophobicity, etc., it is not clear how the results of the delivery of sotalol and salicylate to the skin sheds any light on the delivery of L-arginine or its derivatives to the skin.

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after the foregoing remarks, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.


Application No. 08/932,227
Reply to Final Office Action of January 3, 2008

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Respectfully submitted,

By 
Tani Chen, Sc.D.
Registration No.: 52,728
Patrick R.H. Waller, Ph.D.
Registration No.: 41,418
WOLF, GREENFIELD & SACKS, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
(617) 646-8000